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09/508,239 05/08/00 BERGHOF

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| EXAMINER |
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SQUAYA, J

| ART UNIT | PAPER NUMBER |
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1655

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DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/508,238

Applicant(s)

Berghof et al

Examiner

Jehanne Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 5-17, and 19-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5-17, and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Currently, claims 3, 5-17, and 19-25 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is NON- FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 5-17 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite as it is unclear if the claim is directed to any sequence such that it contains a region that is shorter than SEQ ID NO 1, or to the specific nucleic acid sequences of SEQ ID NOS 3-5 and the complements of such. Claim 3 is further written in improper Markush

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form. The claim should read : ---... the nucleic acid molecule is selected from the group consisting of SEQ ID NOS 3-5 and the complements of SEQ ID NOS 3-5--.

Claim 5 as written is unclear with regard to the phrase "in respect of its sequence". The claim should read --*with* respect to its sequence--.

Claims 8 and 20 are indefinite in the recitation of "where appropriate" because it is unclear what is considered "appropriate" for modification. Neither the claim nor the specification make clear the metes and bounds of claim.

Claims 9 and 21 are indefinite in the recitation of "have been replaced by analogous building blocks known per se as probes or primers" as it is unclear if the 1 or 2 nucleotides have been replaced by probes or primers. It is further unclear what is meant by the term analogous building blocks as it is unclear what the claim considers "analogous" to the nucleotides that are being replaced.

Claim 10 is indefinite with respect to the term "nucleic acid-like" as it is unclear what characteristics the modified groups can possess such that they remain "nucleic-acid-like".

Claim 11 is indefinite in the recitation of "nucleic acid molecule to SEQ ID NO 1" as it is unclear how the nucleic acid molecule in question is related to SEQ ID NO 1. For example, does the claim encompass the isolated nucleic acid molecule of SEQ ID NO 1?

Claim 12 is indefinite as it does not contain any positive active process steps nor does it contain a positive process step relating back to the preamble. The claim merely states a use for an oligonucleotide but does not include any active steps for such use.

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Claim 15 is indefinite because it is unclear where the steps of nucleic acid hybridization, nucleic acid amplification, or both are carried out in the method.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

6. Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number X15400.

The claims as written encompass any nucleic acid molecule that contain 9 of 10 consecutive or 8 of 10 consecutive nucleotides from SEQ ID NOS 3-5 or is 90% homologous to SEQ ID NOS 3-5. Accession number X15400 teaches a sequence that possesses at least 10 consecutive sequences of SEQ ID NO 3.

Response to Arguments

As the term "having" has been interpreted as open terminology, the accession number reads on the claims as presently written.

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New Grounds of Rejection

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 3, 5-11, and 19-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The recitation of "a nucleic acid molecule" reads on a product of nature. This rejection can be overcome by the recitation of "an isolated nucleic acid molecule".

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3, 5-17, and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Firstly, the amendment to claim 3 makes it unclear whether the claim encompasses any nucleic acid sequence comprising a sequence that is shorter than SEQ ID NO 1 or to the specific nucleic acid sequences of SEQ ID NOS 3-5. Furthermore, it is unclear from the claims, whether the term "having" in claim 3 is meant to be "open" or "closed" terminology. Claim 3, prior to amendment, depended from claim 1, wherein the term "having" was considered closed due to the language of claim 1. Claim 3 is now an independent claim, and as the term "having" is not defined in the specification as either "open" or "closed", the term has been interpreted to broadly read on sequences larger than SEQ ID NOS 3, 4, or 5, or the complements of such sequences. The claim as amended thus reads on a sequence "comprising" a shortened sequence compared to SEQ ID NO 1, that being either SEQ ID NOS 3, 4, 5, or the complements of each. In other words, any sequence that is larger than SEQ ID NOS 3, 4, 5, or the complements of such are encompassed by the claims as presently amended. With respect to claim 5, the claim reads even more broadly on sequences that are larger than SEQ ID NOS 3, 4, 5, or the complements of such, wherein the nucleic acid can be only 90% homologous to the sequences encompassed by claim 3, or the nucleic acid need only possess 8 or 9 out of 10 successive nucleotides of the nucleic acid sequence encompassed by claim 3. The claims are further drawn to methods of using such nucleic acids as well as kits comprising such nucleic acids. The specification, however, only teaches the nucleic acid sequence of a *region* of the 23s-5s intergenic spacer from *Pseudomonas aeruginosa*, as well as the nucleic acid sequences *consisting* of the sequences of SEQ ID NOS 3-5. The claimed sequences, however, read on the full intergenic spacer region of 23s-5s from any species

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of *Pseudomonas*, as well as to sequences larger than such up to full length genes from any source. With respect to claims 9 and 22, the claims read on any sequence such that 20% of it's nucleotides can be modified in each string of 10 successive nucleotides. Such a claim would read on a sequence only having 60% complementarity to SEQ ID NO 3.

Furthermore, amendment of claim 3 to -a nucleic acid *consisting of*...-, while overcoming the rejection with respect to claim 3, does not overcome the rejection with respect to claim 5 as the claim would still read on a broad genus of sequences that have not been described in the specification. For example, the molecule of SEQ ID NO 3 consists of 20 nucleotides. Part (ii) of claim 5, however, stipulates that a nucleic acid molecule need only possess 9 out of 10 successive nucleotides of SEQ ID NO 3. Such a molecule could differ from SEQ ID NO 3 in 11 out of 20 positions, thus encompassing a molecule which could read on a probe or primer for a large number of other genes or sequences, from any species of *Pseudomonas*, which have not been described in the specification. The same analysis holds for parts (iii) and (iv) of claim 5.

The claimed invention represents a broad genus for which a representative number of species of such a genus must be disclosed to fulfill the description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date, applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of the isolated nucleic acids of SEQ ID NOS 1 and 3-5, or to methods of using such a broad genus of nucleotides, the specification fails to show

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that applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Claim Rejections - 35 USC § 103

11. Claims 6-17 and 19-25 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Accession number Y00432, March 18, 1991 or Accession number X15400.

Accession number Y00432 teaches a nucleic acid molecule that contains 20 consecutive nucleotides that are identical to SEQ ID NO 2. Although Accession number Y00432 does not teach probes or primers or sequences containing modified oligonucleotides or detectable groups as stated in the claims, it would have been prima facie obvious to construct probes or primers to the known sequences, and to attach or include modified bases for the purposes of amplification and detection of such nucleic acids. Such methods were readily known and used in the art at the time the invention was made.

12. No claims are allowable. Applicant's should further note that many of the claims as written are still grammatically incorrect. Applicant's are urged to telephone the examiner for advice on how to rewrite the claims such that they conform to current US practice.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner

August 27, 2001

[Signature]

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

8/27/01